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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/622,629	10/20/2000	David A. Mark	112701-006	8726

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EXAMINER

SHARAREH, SHAHNAM J

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 07/01/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicant(s)

09/622,629

Applicant(s)

MARK ET AL.

Examiner

Shahnam Sharareh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 28, 2003 has been entered.

Claims 1, 3-15 are pending in this application. Any rejection that is not addressed in this Office Action is considered withdrawn.

Scope of the Pending Claims

Examiner construes the scope of the pending claims to include compositions comprising any protein system so long as at least one of such protein systems consist essentially of whey providing 15%-20% of the energy of the composition. Examiner base such interpretation on the transitional phrase employed in the preamble of the instant compositions. Accordingly, the instant enteral compositions comprise a protein source consisting essentially of whey, a carbohydrate and a lipid source. The instant claims does not exclude the existence of other types of proteins in this composition. Neither does the body of the claim indicate that the whey protein source is the sole source of the protein energy in the instant compositions. Accordingly, instant compositions are interpreted to contain other types of proteins in combination with the instantly claimed amounts of whey protein.

Double Patenting

Claims 1-15 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of copending Application No. 09/759,037. Applicant's intention to file a Terminal Disclaimer is noted when pending claims are allowed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-6, 7, 9-12, 14-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Henningfield et al US Patent 5,221,668

Henningfield discloses liquid nutritional products comprising a protein system which include partially hydrolyzed whey protein such as lactalbumin which provides about 18-24% of its calories (see col 19, lines 28-30). This protein source of Hennigfield consists of lactalbumin which is a whey protein (col 10, lines 31-43). Henningfield's composition also contains lipids in amounts of 20-30% of the calories, and carbohydrates in amounts of 50-58% of the calories (see abstract table 1, col 6 lines 25-40, col 9 lines 31-40, claims 1, 4, 19 and 22). The lipid source of Henningfield is a mixture of medium chain triglyceride and corn oil or canola oil which are known long-chain triglycerides. (see col 12, lines 3-10).

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Henningfield's composition also has a caloric density of about 1.2 to 1.5 Kcal/ml, and a calorie nitrogen ratio of about 112:1 to 145:1 which is above the instantly claimed amounts of at least about 90:1. The product of Henningfield et al also provide sufficient amount of vitamins in 1,500 Kcal (see col 13 lines 40-46, claims 21-22). Henningfield's composition can also contain beta carotene (see claims 22-26). Examiner acquiesces to the fact that Henningfield contains sodicum caseinate as an extras source of protein. However, the scope of the pending claims do not exclude such protein source. Therefore, Henningfield meet the limitations set forth in the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

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were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gray 5,714,472 in view of Schmidl US Patent 5,504,072.

Gray's formulation teaches all elements of the instant claims (see col 7-8, claims 1-15). Gray's formulation only differs in its final concentration of whey protein.

Schmidl reasons for the use of lower amounts of hydrolyzed whey protein in critically ill patients (col 4, lines 51-67). In fact, Schmidl sets forth that it is well known in the art that the nitrogen content of the composition can be measured to best fit the needs of critically ill patients; as indicated by Schmidl et al (see col 6 lines 2-9). Schmidl further teaches the use of all vitamins and minerals that meet the US RDA requirements.

It is well-established that merely selecting proportions and ranges is not patentable absent a showing of criticality. *In re Becket*, 33 USPQ. 33 (C.C.P.A. 1937). *In re Russell*, 439 F.2nd 1228, 169 U.S.P.Q. 426 (C.C.P.A. 1971). Accordingly, absence the showing of criticality, it would have been *prima facie* obvious to optimize the protein concentration of Gray's compositions by routine experimentation, and employ lower amounts of about 16-20% of such proteins, as suggested by Schmidl, because the ordinary artisan would have had a reasonable expectation of success in

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achieving the desirable clinical outcome by modifying the caloric density and nitrogen supply of Gray's compositions.

Claims 1, 3-15 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Henningfield et al US Patent 5,221,668.

The teachings of Henningfield are discussed above. Henningfield teaches the use of zinc, vitamin C, selenium, taurine and L-carnitine (see table 2). Henningfield meets all limitations of the instant claims except the exact amounts of zinc, vitamin C, selenium, taurine and L-carnitine.

It is well-established that merely selecting proportions and ranges is not patentable absent a showing of criticality. *In re Becket*, 33 USPQ. 33. *In re Russell*, 169 U.S.P.Q. 426. It has also been reasoned that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Accordingly, absence of showing the criticality, it would have been obvious to one of ordinary skill in the art at the time of invention to optimize the amounts of such ingredients by routine experimentation, because as reasoned in *Becket*, *Russell* or *Aller*, absence of showing criticality, such optimization is well within the level of the ordinary skill in the art.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose

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telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 703-308-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.



Shahnam Sharareh, PharmD
Patent Examiner, Art Unit 1617

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June 28, 2003